

via phacoemulsification and aspiration prior to addition of self-hardening type chemicals as well as adding new claims directed to a method. The Examiner then stated that the newly presented method claims would not be subject to a restriction requirement.

Applicants now submit a 1.132 declaration by Dr. Sugiura, who is the author of the reference cited against the captioned application. As shown by the 1.132 Declaration by Dr. Sugiura, the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole at the time of invention clearly demonstrate that there was no suggestion or motivation to use the presently claimed gelling compounds.

Applicants have added new claims 10-13 directed to a method of using a pig's eye having an empty lens capsule.

New claims 14-17 contain the dependent limitations of emptying the lens via phacoemulsification and aspiration prior to addition of self-hardening type chemicals and depend from composition claims 1 and 2.

Applicants have also added the limitations at the top of page 4 to the new dependent claims 18 and 19.

Support for claims 18 and 19 can be found in Table 1 at

page 4 of the specification. Support for claims 10-13 can be found at page 5, line 1 of the specification. Support for claims 14-17 can be found at page 5, line 10 of the specification.

Applicants also submit herewith a 1.132 Declaration as requested by the Examiner by Dr. Naomi Nakaki, one of the named inventors of the captioned application, which describes the video evidence provided on CD-ROM during the in-person Interview of June 23, 2003.

Accordingly, Applicants respectfully request the Examiner to enter the amendments and to reconsider and allow all claims pending in this application.

1. Objection of claims 2 and 9  
under 37 C.F.R. § 1.75(c)

The Office Action objects to claims 2 and 9 under 37 C.F.R. § 1.75(c), as being in improper dependent form for failing to further limit the subject matter of a previous claim. The Office Action states:

While applicant attempted to cancel these claims when rewriting the subject matter into independent claims 1 and 3, the clean copy of the claims in Appendix D, which is

the official amendment entered into the file, did not include a cancellation of the claims. Applicant is required to cancel the claims.

Applicants traverse the rejection because claims 2 and 9 were clearly cancelled in the Response of January 30, 2003. The clean copy of the claims in Appendix D shows that claim 2 was cancelled at page 1, line 10 and that claim 9 was cancelled at page 2, line 4.

Accordingly, Applicants request the Examiner to reconsider and withdraw the objection.

2. Rejection of claims 1, 3, 5-6 and 8  
under 35 U.S.C. § 103(a)

The Office Action rejects claims 1, 3, 5-6 and 8 under 35 U.S.C. § 103(a) as being unpatentable over "Creating Cataract in a Pig Eye", J. Refractive Surg., May 1999 ("Sugiura et al.") in view of "Polymer Gelation Due to the Self Assembly of Dibenzylidene Sorbitol and Its Derivatives", Statistical Thermodynamics N.C. State Univ., (June 01, 1999) ("Wilder").

The Office Action states:

Sugiura discloses a model of an eye with cataract comprising a pig's eye which has

hardening chemicals injected into the lens to form the model. Sugiura does not disclose the injection of a self-hardening chemical selected from the group listed in claim 1 into an empty lens. Wilder discloses that dibenzylidene sorbitol is a self-hardening chemical which forms three dimensional fibrillar networks without the need to interact chemically with other substances. It would have been obvious to one of ordinary skill in the relevant art to modify the model disclosed by Sugiura by injecting dibenzylidene sorbitol into an empty lens for the purpose of hardening the eye to produce a simulated cataract without requiring injection into an existing lens. Also, although the location of the injection of claim 5 is not explicitly disclosed by Sugiura, the claimed location does not appear to yield any unexpected advantages over the location disclosed by Sugiura, and thus would also have been obvious to one of ordinary skill in the art as an aesthetic choice of design. Dibenzylidene sorbitol is a known gelling agent which forms three dimensional fibrillar networks in organic substances, as disclosed by Wilder. It would have been obvious to one of ordinary skill in the relevant art to modify the model disclosed by Creating Cataract by providing dibenzylidene sorbitol for the purpose of hardening the eye to produce a simulated cataract.

Applicants respectfully traverse the rejection because the Office Action fails to establish a *prima facie* case of obviousness. In particular, no suggestion or motivation to combine the cited references has been provided. Moreover, as

shown by the 1.132 Declaration by Dr. Sugiura, the knowledge of one of ordinary skill in the art taken in view with the nature of the problem to be solved at the time of invention would not have suggested or motivated the use of the presently claimed compositions.

In particular, the Federal Circuit ruled that a *prima facie* case of obviousness must establish: (1) some suggestion or motivation to modify the references; (2) a reasonable expectation of success; and 3) that the prior art references teach or suggest all claim limitations. Amgen, Inc. v. Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); In re Fine, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

However, when considering whether the element of suggestion or motivation has been met, three possible sources for a motivation to combine references should be considered: (1) the nature of the problem to be solved, (2) the teachings of the prior art, and (3) the knowledge of persons of ordinary skill in the art. In re Rouffet, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). Even though the combination of references teaches each and every element of the claimed invention, without a motivation

to combine, a rejection based on a *prima facie* case of obvious is improper.

Although the level of skill in the art clearly cannot alone be relied upon to provide the suggestion to combine the references, the Examiner must still ascertain whether or not the references would have been sufficient for one of ordinary skill in the art having the reference before him to make the proposed substitution, combination, or other modification. Al-Site Corp. v. VSI Int'l Inc., 50 USPQ2d 1161 (Fed. Cir. 1999); In re Linter, 173 USPQ 560, 562 (CCPA 1972). In other words, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art.

In the present application, the Office Action fails to establish the entire *prima facie* case because one of ordinary skill would not have been motivated to inject dibenzylidene sorbitol into an empty pig's eye.

Wilder only teaches dibenzylidenesorbitol while Sugiura et al. merely teaches hardening crystalline lens proteins with

formalin. There simply is no teaching, suggestion or motivation either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art to use dibenzylidenesorbitol to form a cataract lens.

In support thereof, the 1.132 Declaration by Dr. Sugiura who is the author of the reference cited against the presently claimed invention himself states that the concept of preparing a simulated cataract from a butchered pig's eye using dibenzylidenesorbitol and other polyvalent alcohols is totally different.

Dr. Sugiura notes in the Declaration that the formalin of his teaching requires care in handling whereas the presently claimed polyvalent alcohols are harmless and easier to handle. Dr. Sugiura continues that his compositions are dependent on the type of protein originally existing in the lens whereas the presently claimed compositions allows for alteration in the size and hardness of the simulated cataract by altering the properties and amount of the gelling agents.

Clearly, the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art failed to provide any suggestion or motivation to combine the references. Although the level of

skill in the art alone cannot be relied upon to provide the suggestion to combine the references, it can clearly be seen that the references would not have been sufficient for one of ordinary skill in the art having the references before him to make the proposed substitution, combination, or other modification. Even Dr. Sugiura who is the author of the cited reference states this as fact. Clearly, there is no suggestion or motivation to combine Sugiura et al. and Wilder to make the presently claimed invention.

Accordingly, Applicants respectfully submit that the presently pending claims are unobvious over the cited references and request the Examiner to reconsider and withdraw the rejection against the presently pending claims under 35 U.S.C. §103.

#### CONCLUSION

In light of the foregoing, Applicants submit that the application is now in condition for allowance. The Examiner is therefore respectfully requested to reconsider and withdraw the rejection of the pending claims and allow the pending claims.

USSN 09/834,886  
UMEYAMA et al.

Favorable action with an early allowance of the claims pending  
is earnestly solicited.

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: )  
UMEYAMA; NAKAKI ) Group Art Unit: 3712  
Serial No. 09/834,886 ) Examiner: K. FERNSTROM  
Filed: April 16, 2001 )

For: **A MODEL FOR TRAINING OF SURGICAL OPERATION OF CATARACT**

Appendix A

Please amend the following claims according to the proposed revision of 37 C.F.R. § 1.121 concerning a manner for making claim amendments.

1. (Previously Amended) A model for cataract surgery, comprising: a pig's eye which is prepared by injecting self hardening chemicals selected from the group consisting of dibenzylidenesorbitol, polyhydric alcohol, methylbenzaldehyde, ethyl benzaldehyde and xylitol into a crystalline lens capsule of said pig's eye wherein said crystalline lens capsule of said pig's eye is empty.

2. (Deleted)

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3. (Previously Amended) A model for cataract surgery in the corpus vitreum, wherein a false nucleus of a cataract is prepared by injecting self hardening chemicals selected from the group consisting of dibenzylidenesorbitol, polyhydric alcohol, methylbenzaldehyde, ethyl benzaldehyde and xylitol into an empty crystalline lens capsule of a pig's eye wherein said crystalline lens capsule of said pig's eye is empty.

4. (Deleted)

5. (Previously Amended) The model for cataract surgery of claim 1, wherein said self hardening type chemicals are injected from the posterior pole of said pig's eye.

6. (Previously Amended) The model for cataract surgery of claim 1, wherein the self hardening type chemicals comprise a composition of dibenzylidenesorbitol.

8. (Previously Amended) The model for cataract surgery of claim 3, wherein the self hardening type chemicals comprise a composition mainly comprising dibenzylidenesorbitol.

9. (Deleted)

10. (New) A method of using a pig's eye having an empty crystalline lens capsule, comprising the step of:

injecting self hardening chemicals selected from the group consisting of dibenzylidenesorbitol, polyhydric alcohol, methylbenzaldehyde, ethyl benzaldehyde and xylitol into an empty crystalline lens capsule of the pig's eye wherein said.

11. (New) The method of claim 10, further comprising the step of:

injecting a water soluble cellulose type resin, glycerin and N-methyl-2-pyrrolidone into the empty crystalline lens capsule of the pig's eye.

12. (New) The method of claim 10, wherein said crystalline eye is emptied by phacoemulsification.

13. (New) The method of claim 10, wherein said crystalline eye is emptied by aspiration.

14. (New) The model for cataract surgery of claim 1, wherein said crystalline lens of the pig's eye is emptied by phacoemulsification.

15. (New) The model for cataract surgery of claim 1, wherein said crystalline lens of the pig's eye is emptied by aspiration.

16. (New) The model for cataract surgery of claim 3, wherein said crystalline lens of the pig's eye is emptied by phacoemulsification.

17. (New) The model for cataract surgery of claim 3, wherein said crystalline lens of the pig's eye is emptied by aspiration.

18. (New) The model for cataract surgery of claim 1, comprising:

a water soluble cellulose type resin, glycerin and N-methyl-2-pyrrolidone.

19. (New) The model for cataract surgery of claim 3, comprising:

a water soluble cellulose type resin, glycerin and N-methyl-2-pyrrolidone.